

U.S.S.N. 09/852,966
Attorney Docket No.: AVZ-020CN

Examiner: Vickie Kim
Group Art Unit: 1614

REMARKS

Claims 68-88 were pending. Claims 71 and 74 were cancelled. Claims 68-70, 72 and 73 were amended. Therefore, claims 68-70, 72, 73, and 75-88 are currently pending.

No new matter has been added. Claims 68-70, 72 and 73 were amended to clarify the invention.

Applicant gratefully acknowledges the telephonic interview between the Examiner and Applicant's attorney, Elizabeth Hanley, on June 19, 2003. The amendments of the claims herein were discussed with the Examiner during the interview.

Rejection of Claims 68-71, 74, and 84-87 under 35 U.S.C. § 102(b)

Claims 68-71, 74, and 84-87 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Lee et al.* (U.S. 5,605,687). Claim 71 and 74 were cancelled thus rendering their rejection moot.

Claim 68 and its dependent claims are directed to method for increasing energy reserves in the skin of a subject. The method includes administering to the subject an effective amount of creatine or a salt thereof. Claim 69 is directed to a method for sustaining energy production in the skin of a subject. The method includes administering to the subject an effective amount of creatine. Claim 70 is directed to a method for modulating energy flow in the skin of a subject. The method includes administering to a subject an effective amount of creatine or a salt thereof, such that the energy flow in the skin of said subject is modulated.

Lee et al. describe methods for the treatment of tissue damage resulting from cell membrane permeabilization due to electrical injury using a surface active copolymer and a high energy phosphate compound. *Lee et al.* fails to teach or suggest methods of using creatine and its salts, as claimed by Applicant. Furthermore, *Lee et al.* fails to teach or suggest methods using creatine or salts thereof to increase energy reserves in the skin of a subject, sustain energy production in the skin of a subject, or modulate energy flow in the skin of a subject, as claimed by Applicant.

Therefore, Applicant respectfully requests that this rejection of claims 68-70, and 84-87 under 35 U.S.C. § 102 (b) be withdrawn.

Rejection of Claims 68-88 under 35 U.S.C. § 103(a)

Claims 68-88 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lee et al.* in view of *Hoppe et al.* (U.S. 6,261,575). Claims 71 and 74 have been cancelled, thus rendering their rejection moot.

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As described above, Applicant's claims are directed to methods for increasing energy reserves in the skin of a subject, sustaining energy production in the skin of a subject, and modulating energy flow in the skin of a subject. The methods include administering to a subject an effective amount of creatine or a salt thereof.

As described above, Lee *et al.* describes methods for the treatment of tissue damage resulting from cell membrane permeabilization due to electrical injury using a surface active copolymer and a high energy phosphate compound. Lee *et al.* fails to teach or suggest methods using creatine or salts thereof as claimed by Applicant.

Hoppe *et al.* fails to overcome the deficiencies of Lee *et al.* Hoppe *et al.* is directed to topical formulations comprising a sterol or a biochemical precursor thereof in combination with a ubiquinone, ubiquinone derivative, plastoquinone, or a plastoquinone derivative. Although Hoppe *et al.* mentions creatine as a possible additive, Hoppe *et al.* states that the invention relates to "combinations which contain sterols and biochemical precursors thereof in combination with ubiquinones and/or plastoquinones." Hoppe *et al.* fail to teach or suggest *methods* which include administering an effective amount of creatine or a salt thereof, as claimed by Applicant.

Hoppe *et al.*, alone or in combination with Lee *et al.*, fails to teach a method comprising administering to a subject an effective amount of creatine or a salt thereof, such that energy reserves in the skin of a subject are increased, energy production in the skin of a subject is sustained, or energy flow in the skin of a subject is modulated.

Therefore, Applicant requests that this rejection of claims 68-70, 72, 73, and 75-88 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 68-88 under 35 U.S.C. § 103(a)

Claims 68-88 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Greff (FR 2725896), in view of Yu *et al.* (U.S. 5,886,041) or Hoppe *et al.* Claims 71 and 74 have been cancelled, thus rendering their rejection moot.

As described above, Applicant's claims are directed to methods for increasing energy reserves in the skin of a subject, sustaining energy production in the skin of a subject, and modulating energy flow in the skin of a subject. The methods include administering to a subject an effective amount of creatine or a salt thereof.

Greff describes the use of fermentation products containing amino acids in cosmetic compositions for stimulating phosphocreatine synthesis, stimulation of cellular growth, and reducing skin wrinkles. Greff fails to teach or suggest methods using an effective amount of creatine or its salts as claimed by Applicant.

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Greff fails to teach or suggest Applicant's claimed methods which include administering an effective amount of creatine or a salt thereof such that energy reserves in the skin of a subject are increased, energy production in the skin of a subject is sustained, or energy flow in the skin of a subject is modulated.

Yu *et al.* is directed to methods of treating skin disorders using pH balanced compositions of alphaketo acids and alphahydroxy acids. It is directed to methods and compositions using a wide variety of organic and inorganic amphoteric compounds, including creatine, to enhance the skin penetration of the "active" ingredients, i.e., alphaketoacids and alphahydroxy acids.

Yu *et al.* fails to teach or suggest that amphoteric compounds, such as creatine, would be useful in any other capacity other than to balance the pH and enhance the ability of the alphaketo acids and the alphahydroxy acids to penetrate the skin. Yu *et al.* fails to teach or suggest the claimed methods using an effective amount of creatine. Yu *et al.* emphasizes that the active compounds are the alphahydroxy acids and the alphaketo acids. Therefore, it fails to teach or suggest a *method* of using an of creatine or a salt thereof to increase energy reserves in the skin of a subject, sustain energy production in the skin of a subject, or modulate energy flow in the skin of a subject.

Hoppe *et al.* fails to overcome the deficiencies of Lee *et al.* Hoppe *et al.* is directed to topical formulations comprising a sterol or a biochemical precursor thereof in combination with a ubiquinone, ubiquinone derivative, plastoquinone, or a plastoquinone derivative. Although, like Yu *et al.*, Hoppe *et al.* mentions creatine as a possible additive, Hoppe *et al.* does not describe methods using an effective amount of creatine to increase energy reserves in the skin of a subject, sustain energy production in the skin of a subject, or modulate energy flow in the skin of a subject.

Although both Hoppe *et al.* and Yu *et al.* mention creatine as a possible additive, both of the references, alone or in combination, fail to overcome the deficiency of the primary reference. The references, alone or in combination, fail to teach or suggest Applicant's claimed methods of administering to a subject an effective amount of creatine or a salt thereof such that energy reserves in the skin of a subject are increased, energy production in the skin of a subject is sustained, or energy flow in the skin of a subject is modulated.

Therefore, Applicant requests that this rejection of claims 68-70, 72, 73, and 75-88 under 35 U.S.C. § 103(a) be withdrawn.

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Rejection of Claims 68-88 under Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 68-88 were rejected under the judicially created doctrine of obviousness type double patenting over claims of U.S. Patent No. 6,242,491. The Office Action indicates that a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.312 (c) may be used to overcome a rejection based on a non-statutory double patenting ground provided the patent is shown to be commonly owned with this application. Applicants will address the double patenting issue upon a finding of subject matter in the instant application that is allowable but for the double patenting rejection.


SUMMARY

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims is being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The amendments made to the claims are not related to any issues of patentability.

In view of the above remarks and amendments, it is believed that this application is in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Elizabeth A. Hanley, Esq. at (617) 227-7400.

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